

## **REMARKS**

### ***In the Drawings***

The drawings were objected to under 37 C.F.R. 1.83(a). In particular, the Examiner asserts that “the mouthpiece which includes a flexible member which is deflectable on exhalation claimed in claims 38-43 must be shown or the feature(s) cancelled from the claim(s).”

Applicant submits that the flexible member of claims 38-43 is disclosed in the specification such that amendment of the drawings is unnecessary. See, e.g., page 17, lines 10-16 of the specification, which describes an embodiment in which the mouthpiece 31 includes a flexible member in the form of “a diaphragm which is acted upon by the exhalation breath of the subject to actuate the trigger mechanism 55 ....”

Accordingly, Applicant respectfully requests that the objection to the drawings be reconsidered and withdrawn.

### ***Double Patenting***

#### ***U.S. Patent No. 6,715,485***

Claims 28 and 35 were rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 6 of U.S. Patent No. 6,715,485.

Claim 6 is directed to a supply unit for delivering a gas flow separate to an exhalation flow.

The subject-matter of claim 28 is patentably distinct from claim 6 because claim 28 recites the cycling of a pressure in the nasal airway of the subject. Claim 6 provides only for the delivery of a gas flow, and not the cycling of a pressure in the nasal airway.

The subject-matter of claim 35 is patentably distinct from claim 6 because claim 35 recites alternate delivery and withdrawal of a volume of gas through the nasal airway of the subject. Claim 6 provides only for the delivery of a gas flow, and not withdrawal of that gas flow.

Accordingly, Applicant respectfully requests that the double patenting rejection of claims 28 and 35 be reconsidered and withdrawn.

***Application No. 10/520,380 and Keldmann***

Claims 38-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 86-87 and 89 of co-pending Application No. 10/520,380 and further in view of Keldmann et al., WO 98/53869 A1 (“Keldmann”).

Applicant respectfully submits that the instant claims 38-41 define patentably distinct subject matter from claims 86-87 and 89 of co-pending Application No. 10/520,380 because there are numerous differences in the interface members defined by the respective sets of claims. For example, one fundamental difference is that claims 38-41 are directed to a discrete “interface member” designed for attachment to a nasal delivery device, whereas claims 86-87 and 89 are directed to a nasal delivery device comprising, among other things, a “disposable interface unit.”

Accordingly, Applicant respectfully requests that the provisional double patenting rejection of claim 38-41 be reconsidered and withdrawn.

***Claim Rejections – 35 U.S.C. § 102***

***Alving, claims 1-37***

Claims 1-37 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,019,100 to Alving et al. (“Alving”). Applicant respectfully disagrees, as Alving does not disclose every element of Applicant’s independent claims.

At the very least, Alving does not disclose the following claim elements:

- Claim 1: a mouthpiece through which the subject in use exhales to cause closure of the oropharyngeal velum of the subject during delivery of substance;
- Claim 16: the step of exhaling through a mouthpiece during delivery of substance to cause closure of the oropharyngeal velum of the subject;
- Claim 28: a mouthpiece through which a subject in use exhales to cause closure of the oropharyngeal velum of the subject;

- Claim 31: the step of exhaling through a mouthpiece during delivery of substance to cause closure of the oropharyngeal velum of the subject;
- Claim 35: a mouthpiece through which a subject in use exhales to cause closure of the oropharyngeal velum of the subject; and
- Claim 36: the step of exhaling through a mouthpiece during delivery of substance to cause closure of the oropharyngeal velum of the subject.

The Examiner alleges that Alving's element 9 discloses Applicant's claimed mouthpiece. However, Alving does not teach or suggest such a mouthpiece. Alving discloses methods and apparatuses relating to intubated or tracheostomized patients. See column 4, line 44 and claims 1-23. For example, Alving discloses that the ventilator is connected to an endotracheal tube 9 cuffed in the trachea of a patient. See column 5, lines 19-23. Exhalation through the endotracheal tube 9 does not cause closure of the oropharyngeal velum of the subject as recited by the pending claims, but only the development of an air flow through the respiratory tube 8.

Accordingly, Applicant respectfully requests that the rejection of claims 1-37 based on Alving be reconsidered and withdrawn.

***Djupestrand, claims 28-35***

Claims 28-35 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Djupestrand, WO 00/51672 ("Djupestrand"). Applicant respectfully disagrees, as Djupestrand does not disclose every element of the independent claims.

At the very least, Djupestrand does not disclose the following claim elements:

- Claim 28: a gas supply unit for cycling a pressure in the nasal airway of the subject on exhalation by the subject;
- Claim 31: the step of cycling a pressure in the nasal airway of the subject; and
- Claim 35: a gas supply unit for alternately delivering and withdrawing a volume of gas through the nasal airway of the subject on exhalation by the subject, such as to cause entrained substance to be flushed in alternate directions therethrough.

The Examiner apparently alleges that Djupesland's elements **28** and **32** disclose Applicant's recited gas supply unit for cycling a pressure in the subject's nasal airway, and presumably for alternately delivering and withdrawing a volume of gas. In particular, the Examiner points to Djupesland at page 7, line 4 to page 10, line 10 and page 17, line 15 to page 19, line 13. However, these passages do not teach or suggest the foregoing claim elements.

Djupesland's flow resistor **28** functions "to provide a sufficient resistance to exhalation therethrough by a subject as to cause the generation of a positive pressure in the oral cavity of the subject and the closure of the velum on exhalation by the subject." (Djupesland at page 17, lines 28-30.) Djupesland's medicament supply unit **32** functions to supply "a gas flow entraining medicament at a predetermined pressure sufficient to open a flow path beyond the posterior margin of the nasal septum when delivered into one of the nasal cavities of the subject ...." (Djupesland at page 18, lines 6-9.) These elements and their functions are entirely different, and do not even suggest, the elements of pressure cycling and alternate delivery and withdrawal of a volume of gas through the subject's nasal airway.

Accordingly, Applicant respectfully requests that the anticipation rejection of claim **28-35** based on Djupesland be reconsidered and withdrawn.

***Keldmann, claims 38 and 40-43***

Claims **38** and **40-43** were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Keldmann. Applicant respectfully disagrees, as Keldmann does not disclose every element of the independent claim **38**.

At the very least, Keldmann does not disclose a mouthpiece including a flexible member which is deflectable on exhalation into the mouthpiece so as to trigger a substance supply unit in the nasal delivery device, and further, an integral element configured such that no part of the delivery device to which it is attached is exposed to the exhalation breath of the subject.

Accordingly, Applicant respectfully requests that the anticipation rejection of claim **38** and **40-43** based on Keldmann be reconsidered and withdrawn.

***Claim Rejections – 35 U.S.C. § 103***

***Djupesland and the specification, claims 38 and 40-43***

Claims 38 and 40-43 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Djupesland as applied to claims 28-35 above and further in view of “suggestions in the specification.” Applicant respectfully disagrees.

Claims 38 and 40-43 are not obvious in view of Djupesland, because Djupesland does not teach or suggest every element of claims 38 and 40-43. At a minimum, Djupesland does not teach or suggest a mouthpiece including a flexible member which is deflectable on exhalation into the mouthpiece so as to trigger a substance supply unit in the nasal delivery device.

Accordingly, Applicant respectfully requests that the obviousness rejection of claims 38 and 40-43 based on Djupesland in view of “suggestions in the specification” be reconsidered and withdrawn.

***Alving and Djupesland, claim 39***

Claim 39 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Alving as applied to claims 1-37 above and further in view of Djupesland.

Claim 39 is allowable as depending upon allowable base claim 38.

Accordingly, Applicant respectfully requests that the obviousness rejection of claim 39 based on Alving in view of Djupesland be reconsidered and withdrawn.

**CONCLUSION**

Applicant respectfully submits that all pending claims are in condition for allowance and requests early favorable action. If the Examiner believes a telephonic interview would expedite prosecution, the Examiner is welcome to contact Applicant's Agent at the number below.

Respectfully submitted,

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